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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,094	07/06/2001	Ramaswamy Murari	DEL-062B	4448

7590

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,094

Applicant(s)

MURARI ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 13, the phrase "stamp-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "stamp-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pletcher et al (USPN 6074688) in view of Chen et al (USPN 5225294) and Rudnic et al (USPN 5430021). Claims 1-13 are drawn to a method of formulating a thyroid hormone dosage and the hormone dosage itself. The method comprises electrostatically binding a dry powdered form of a thyroid hormone onto an acceptable polymer. Specifically the polymer must have received GRAS approval and be non-reactive to the amino or iodo group of the thyroid hormones. The claims also recite that the powder must be substantially free of excipients and have average particles less than 5 μ .

Pletcher et al discloses a method for electrostatically binding a powdered medicament to a substrate. Specifically the deposition of a powdered medicament onto the surface of a tablet optionally coated with a synthetic polymer (preferably hydroxypropylcellulose or hydroxypropylmethylcellulose). Once the medicament is deposited onto the substrate, Pletcher discloses that the substrate/medicament combination can be encapsulated in an inert material to form a tablet (column 3, lines 39-column 4, lines 27; column 5, lines 60-64; column 12, lines 58-61). Though Pletcher discloses the method and substrate of the claimed invention, it does not specifically disclose or suggest the nature of the powdered medicament used, specifically the particle size or variety of medicament. Though the medicament is not named, it can be assumed that methods of Pletcher can be substituted with any powdered medicament compatible with cellulose based synthetic resins.

Rudnic et al (USPN 5430021) discloses a pharmaceutical preparation that can be made into tablets, comprising a thyroid-releasing hormone in powdered form, and a hydroxypropylmethylcellulose coating. The thyroid hormone powder particles generally

have a size from 0.5 –100 microns, most preferably 0.5-10 microns (column 3, lines 53-59; claim 7). Though the cellulose derivative is used as a coating for the particles in the reference their compatibility allows for particles to be used in the methods disclosed in Pletcher. Also deficient from this reference is the specific thyroid hormone.

Chen et al (USPN 5225294) discloses a dosage form of levothyroxine sodium. The hormone is granulated and adsorbed onto the surface of a cellulose carrier, namely hydroxypropylmethylcellulose (Abstract, column 3, lines 26-30). Though Chen discloses the powder and substrate of the claimed invention, the reference is silent to the size of the hormone particles.

One of ordinary skill in the art would have been motivated to combine the teachings of Pletcher with the suggestions and disclosures of Rudnic and Chen, by substituting the particles of levothyroxine sodium of Chen with the particles of Rudnic and further substitute those into the methods of Pletcher; all of this in order to impart stable medicinal, therapeutic properties onto a flexible, bio-available polymer. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teaching and suggestions in this fashion with the expected result of a stable thyroid formulation comprising a flexible, bio-available polymer able to treat hypothalamic disorders without degrading.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-5014.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
March 19, 2002


THOMAS K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600